

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Mar-2019
Document Type: USP Monographs
DocId: GUID-5C198D14-B5D0-4674-8C66-0A1D63F89380_5_en-US
DOI: https://doi.org/10.31003/USPNF_M11863_05_01
DOI Ref: 6mh66

© 2025 USPC
Do not distribute

Add the following:

^Mirtazapine Compounded Oral Suspension, Veterinary

DEFINITION

Mirtazapine Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of mirtazapine ($C_{17}H_{19}N_3$).
Prepare Mirtazapine Compounded Oral Suspension, Veterinary 10 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Mirtazapine tablet(s), ^a equivalent to	1.2 g of mirtazapine
Vehicle: 1:1 mixture of Ora-Plus ^b and Ora-Sweet, ^b a sufficient quantity to make	120 mL

- ^a Mirtazapine 30-mg tablets, Mylan Pharmaceuticals, Inc., Morgantown, WV.
^b Perrigo, Allegan, MI.

Place the *Mirtazapine tablets* in a suitable container and triturate to a fine powder. Add a small amount of *Vehicle* and mix well to form a smooth paste. Add a sufficient amount of *Vehicle* to make the contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Mix well.

ASSAY

• PROCEDURE

Mobile phase: Add 23.5 mL of 25% tetramethylammonium hydroxide solution to 626.5 mL of water. Adjust with phosphoric acid to a pH of 7.4. Add 150 mL of acetonitrile, 125 mL of methanol, and 75 mL of tetrahydrofuran.

Diluent: Acetonitrile and water (50:50)

Standard solution: 0.5 mg/mL of USP Mirtazapine RS in *Diluent*

Sample solution: Transfer 0.5 mL of Oral Suspension, Veterinary to a 10-mL volumetric flask, and add *Diluent* to volume. Pass through a filter of 0.22-µm pore size.

Chromatographic system
(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 295 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 60°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for mirtazapine is about 25.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of mirtazapine ($C_{17}H_{19}N_3$) in the portion of Oral Suspension, Veterinary taken:

Result = $(r_U/r_S) \times (C_S/C_U) \times 100$

r_U = peak response of mirtazapine from the *Sample solution*

r_S = peak response of mirtazapine from the *Standard solution*

C_S = concentration of USP Mirtazapine RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of mirtazapine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [pH \(791\)](#): 5.6–6.6

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at controlled room temperature or in a refrigerator.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at controlled room temperature or in a refrigerator.
- **LABELING:** Label it to state that it is to be well shaken before use, and to state the *Beyond-Use Date*. Label it to state that it is for veterinary use only.
- **USP REFERENCE STANDARDS (11).**
[USP Mirtazapine RS](#)
 ▲2S (USP41)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MIRTAZAPINE COMPOUNDED ORAL SUSPENSION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 43(5)

Current DocID: GUID-5C198D14-B5D0-4674-8C66-0A1D63F89380_5_en-US

Previous DocID: GUID-5C198D14-B5D0-4674-8C66-0A1D63F89380_2_en-US

DOI: https://doi.org/10.31003/USPNF_M11863_05_01

DOI ref: [6mh66](#)